System	Sequence	Organism	Source	Reference
Infectious disease antigens	GLLGWSPQA	HBV	Env 62	Bertoni et al., J Clin Invest 100: 503, 1997
	FLLAQFTSA	HBV	Pol 503	Livingston et al., unpublished observations
	YMDDVVLGA	HBV	Pol 538	Rehermann et al., J Clin Invest 97: 1655, 1996
	LLFLLLADA	HCV	NS1/E2 726	Scognamiglio et al., J Immunol 162: 6681, 1999
	VLVGGVLAA	HCV	NS4 1666	Scognamiglio et al., J Immunol 162: 6681, 1999
	WMNRLIAFA	HCV	NS4 1920	Scognamiglio et al., J Immunol 162: 6681, 1999
	LTFGWCFKLV	HIV	Nef 62	Altfeld et al., J Virol 75: 1301, 2001
	LVGPTPVNI	HIV	Pol 100	Altfeld et al., J Virol 75: 1301, 2001
	YTAFTIPSI	HIV	Pol 83	Altfeld et al., J Virol 75: 1301, 2001
	KLVGKLNWA	HIV	Pol 87	
	RILQQLLFI	HIV	Vpr 72	Altfeld et al., J Virol 75: 1301, 2001
	AIIRILQQL	HIV	Vpr 76	Altfeld et al., J Virol 75: 1301, 2001
	MINAYLDKL	P. falciparum	STARP	Gonzalez et al., Parasite Immunol 22: 501, 2000
	KILSVFFLA	P. falciparum	EXP1 2	Doolan et al., Immunity 7: 97, 1997
	LIFFDLFLV	P. falciparum	SSP2 15	Doolan et al., Immunity 7: 97, 1997; Sette et al., unpublished observations[a]
	FVNHDFTVV	T. cruzi	ASP-1 508	Wizel et al., J Clin Invest 102: 1062, 1998
	IAGGVMAVV	T. cruzi	ASP-1 71	Wizel et al., J Clin Invest 102: 1062, 1998
	WVFPESISPV	T. cruzi	ASP-2 302	Wizel et al., J Clin Invest 102: 1062, 1998
	FVNHRFTLV	T. cruzi	ASP-2 551	Wizel et al., J Clin Invest 102: 1062, 1998
	FVDYNFTIV	T. cruzi	TSA-1 514	Wizel et al., J Clin Invest 102: 1062, 1998
Tumor associated antigens	TIHDIILECV	HPV	E6 29	Ressing et al., J Immunol 154: 5934, 1995
	FAFKDLFVV	HPV	E6 47	Castellanos et al., Gynec Oncol 82: 77, 2001
	FAFRDLCIV	HPV	E6 52	Ressing et al., J Immunol 154: 5934, 1995
	KATLQDIVLHL	HPV	E7 5	Castellanos et al., Crit Rev Oncol/Hemat 39: 133, 2001
	GTLGIVCPI	HPV	E7 85	Wentworth et al., Eur J Immunol 26: 97, 1996
	KTWGQYWQV	Human	gp100 154	Kawakami et al., J Immunol 154: 3961, 1995
	ITDQVPFSV	Human	gp100 209	Kawakami et al., J Immunol 154: 3961, 1995
	YLEPGPVTA	Human	gp100 280	Kawakami et al., J Immunol 154: 3961, 1995
	KIFGSLAFL	Human	HER2 369	Kawashima et al., Human Immunol 59: 1, 1998
	KIFGSLAFL	Human	Her-2/neu 369	Lustgarten et al., Human Immunol 52: 109, 1997
	KIWEELSML	Human	MAGE2 220	Fikes et al., unpublished observations
	KVAELVHFL	Human	MAGE3 112	Kawashima et al., Human Immunol 59: 1, 1998
	AAGIGILTV	Human	MART1 27	Rivoltini et al., J Immunol 154: 2257, 1995
	AARAVFLAL	Human	Tyrosinase	Boel et al., Immunity 2: 167, 1995

a. Epitope described in the literature nested the peptide indicated.

EXHIBIT B

PATENT
Docket No. 399632000623

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, November 15, 2001.

Rebekah Werth
Rebekah Werth

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Howard M. GREY, *et al.*

Serial No.: 08/349,177

Filing Date: 2 December 1994

For: HLA-A2.1 BINDING PEPTIDES AND THEIR USES

Examiner: Ron Schwadron

Group Art Unit: 1644

DECLARATION OF ALESSANDRO SETTE PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Alessandro Sette, Ph. D., declare as follows:

1. I am a co-inventor of the subject matter claimed in the above-referenced application and am employed by Epimmune, Inc., the assignee. I have researched antigen processing, antigen recognition and specificity, and antigen presentation in the field of immunology for 20 years, and a copy of my *curriculum vitae* is attached hereto as Exhibit A. I have published over 200 papers in this field. Moreover, my two first publications on the subject matter of the present application, Ruppert *et al., Cell* (1993) 74:929-937 and Kast *et al., J. Immunol.* (1994) 152:3904-3912, have been cited in over 439 subsequent publications.

2. The herein application, U.S. Serial No. 08/349,177, filed 2 December 1994 (the '177 application) claims priority through a series of co-pending applications to U.S. Serial No. 08/027,146 filed 5 March 1993 (the '146 application). The disclosure of the '146 application is incorporated by reference into the present application and I have been informed that the claims proposed in the '177 application are supported by the disclosure of the '146 application. I will therefore discuss the state of the art as it stood in March of 1993.

3. I have been informed that the Office, in its most recent action, asserts that undue experimentation would be required to identify which peptides containing the disclosed and claimed HLA-A2.1 binding motif would be immunogenic in subjects expressing the HLA-A2.1 antigen. As exemplified by the data set forth below, as of March 1993, only routine experimentation would be required to identify these peptides and methods for screening any particular peptide for CTL induction and recognition were well known and routinely practiced. Further, as is evident from the discussion in the specification, peptides which exhibit the disclosed HLA-A2.1 binding motifs are more likely than peptides not possessing these motifs to exhibit immunogenicity. Thus, a method to identify suitable peptides containing these motifs is of value in reducing the experimentation required to find, by the routine experimentation available in the art, those peptides which are actually immunogenic in the appropriate subjects.

4. Numerous publications predating March of 1993 describe the routine use of various methods, some of which were described in the specification as a convenience to the reader, to ascertain whether an individual peptide is or is not immunogenic in subjects exhibiting the appropriate HLA antigen. These assays can be conducted both *in vitro* and *in vivo*. Hogan, *et al., J. Exp. Med.* (1988) 168:725 assayed peptides for the ability to induce and HLA restricted primary response in CTL's from normal donors. Bertoletti, *et al., Proc. Natl. Acad. Sci. USA*

(1991) 88:10445-10449 and Hill, *et al., Nature* (1992) 360:434-439 assayed the ability of a variety of peptides to serve as targets for lysis by CTL's isolated from infected donors. Vitiello, *et al., J. Exp. Med.* (1991) 173:1007-1015 and Engelhard, *et al., J. Immunol.* (1991) 146:1226-1232 describe assessing immunogenicity by immunizing mice that carry an appropriate HLA transgene with a test protein or peptide. Culmann, *et al., J. Immunol.* (1991) 146:1560-1565, in order to identify epitopes that were recognized by CTL's specific for HIV NEF protein incubated radiolabeled target cells with 33 synthetic peptides and measured lysis by NEF-specific CTL from 0+ donors. They found at least 5 of the 33 peptides were recognized by donor CTL's.

5. In all the foregoing cases, the testing to decide whether any particular peptide is or is not immunogenic was carried out in a routine manner without difficulty or innovative experimentation.

6. It was also recognized that anchor residues defining the binding motif were necessary, but not necessarily sufficient, for high affinity HLA binding Jameson, *et al., Eur. J. Immunol.* (1992) 22: 2663-2667. Thus, investigators appreciated the need to determine empirically, *e.g.*, through screening assays, whether any particular peptide identified by motif analysis would actually bind a MHC molecule and induce a CTL response. It was also understood that the ability of a peptide to bind a particular HLA antigen would be useful to rule out non-binding peptides as potential immunogens. Such screening assays were also routine as described by Benjamin, *et al., Nature* (1991) 351:74-78, using intact cells; by Cerundolo, *et al., Eur. J. Immunol.* (1991) 21:2069-2075 using cell extracts and by Corr, *et al., J. Exp. Med.* (1992) 176:1681-1692 using purified class I molecules. However, as it is also known that binding of the appropriate class I MHC molecule is necessary but not sufficient to ensure immunogenicity, the

routine assays described in the documents set forth above in paragraph 4 were routinely used to separate those binders which are immunogenic from those which are not.

7. For example, Hill, *et al., Nature* (1992) 360:434-443 (cited in paragraph 4) synthesized 60 peptides derived from *Plasmodium falciparum* antigens and used HLA-B53 binding assays to eliminate the non-binding peptides. Eight of the 60 candidate peptides were positive in the HLA binding assay, and were tested for the ability to be recognized by CTL's from adults exposed to *P. falciparum.* The investigators determined that at least 1 of the 8 HLA-B53 restricted peptides was able to serve as a target for lysis by these CTL's. This approach enabled the identification of an epitope recognized by CTL that Hill, *et al.*, suggested "may account for a substantial part of the HLA-B53 protective association" in malaria.

8. In another example, Lipford, *et al., J. Immunol.* (1993) 150:1212-1222, analyzed 5 peptides derived from ovalbumin for the ability to bind mouse MHC class I molecule, H2-K^b, and found that 3 were able to form complexes with the appropriate MHC class I molecule. To test the natural antigenicity of the peptides, the investigators immunized C57BL/6 mice with ovalbumin containing immunostimulating complexes to elicit an MHC class I-driven response to naturally processed ovalbumin. The cytolytic potential of the responding T cell population was tested *in vitro* by using EL-4 cells preincubated with the predicted synthetic peptides as targets. Using these assays, they determined that at least 2 of the 3 MHC class I-binding peptides were also antigenic.

9. These papers demonstrate that immunogenicity or antigenicity assays are neither difficult nor burdensome. Other examples of investigators routinely screening for immunogenic or antigenic peptides can be seen in the works of Banks, *et al., J. Virol.* (1993) 67(1):613-616, Cossins, *et al., Virology* (1993) 193(1):289-295 and Pamer, *et al., Nature*, (1991) 353(6347):792.

10. It has become increasingly apparent that even the routine experimentation required to verify immunogenicity of a particular peptide can be minimized if the protocols suggested in the '146 application are carried out - *i.e.*, if candidate peptides are identified based on a binding motif characteristic of the HLA restriction at issue, and then this subset of candidates further screened for their ability actually to bind the relevant HLA antigen. In March of 1993, it was known that peptides with the same HLA-binding specificity share certain conserved residues, often referred to as peptide motifs or anchor residues, although what these residues are was not known for all alleles. These motifs have been elucidated over the years. For example, Kast, *et al., J. Immunol.* (1994) 152:3904 demonstrated that essentially all HLA-A binding peptides conform to specific motifs. Specifically, Kast and colleagues synthesized all possible 9-mer peptides derived from the E6 and E7 proteins of HPV-18 and tested them for binding to HLA-A1, A2.1, A3, A11 and A24. They measured 1200 peptide/HLA binding affinities and found 22 (1.8%) had an affinity of 500 nM or less and 7 (0.6%) had an affinity of 50 nM or less. Ninety-one percent of the peptides binding at the 500 nM level and 100% of the peptides binding at the 50 nM level carried specific HLA motifs. Thus, they concluded that essentially all peptides binding HLA carry specific motifs. Motif analysis would have predicted 111 HLA/peptide combinations, and thus would have reduced by 10.8-fold the number of HLA/peptide interactions to be measured. The probability that a peptide will bind to a particular HLA molecule dramatically increases when the peptide sequence conforms to a specified HLA motif. Therefore, sequence analysis using a known motif reduces the amount of screening required to identify those peptides that bind an HLA recognizing that motif.

11. Moreover, later investigators identified potential CTL-inducing or CTL-recognized peptides by the combination of motif analysis and HLA-binding assays. As

discussed above, through this strategy, Hill, *et al.* initially identified 60 candidate HLA-B53 peptides by motif analysis, determined that at least 8 of the candidates bound to HLA molecules, and verified at least 1 peptide as being immunogenic. Similarly, DiBrino, *et al., J. Immunol.* (1994) 152:620 identified 7 candidate peptides containing motifs, determined that at least 4 bound to an HLA molecule, and determined that at least 3 of the 4 HLA-binding peptides were immunogenic. Celis, *et al., Proc. Natl. Acad. Sci USA* (1994) 91:215-9 identified 10 candidates, determined that at least 6 bound to HLA, and that at least 1 of the HLA-binding candidates was immunogenic. Others have also reported potential CTL-inducing or CTL- recognized peptides by the combination of motif analysis and HLA-binding assays: Chang, *J. Immunol.* (1991) 162:1156; Threlk *et al., J. Immunol.* (1997) 159:1648; Bertoni *et al., J. Clin. Invest.* (1998) 100:503; Wizel *et al., J. Clin. Invest.* (1998) 102:1062; Scognamiglio *et al., J. Immunol.* (1999) 162:6681; and Doolan *et al., Immunity* (1997) 7:97.

12. The work described above shows that investigators successfully used the combination of motif analysis and HLA-binding assays to identify immunogenic or antigenic peptides. It also demonstrates that finding only one or a few "hits" out of as many as 60 test molecules was not considered a rare or unusual event by researchers in this field.

13. The success of the approach of using a particular motif to identify candidate peptides that bind to a particular HLA antigen, testing the binding to that antigen, and then testing successful binders for immunogenicity is that described in the specification of the '146 application at page 10, line 23 to page 12, line 8. The contribution of the present invention is to discover that the anchor residues at position 2 and the C-terminus of the immunogenic peptide can be expanded from the art-known residues. At position 2 the list of known residues, L and M, could be expanded to include I, V, A and T and that the art-known residues at the C-terminus, V,

L and I could be expanded to include A and M. Using this information, additional immunogenic peptides can be identified and tested according to the described method of the invention. This has been verified as set forth below in paragraphs 15-17.

14. Additionally, the predictability of the motif has been enhanced by the identification of the appropriate secondary anchor residues as claimed in the dependent claims.

15. Not only has the paradigm of starting from a motif, proceeding to test binding to the desired HLA antigen, and verifying immunogenicity in routine assays been used successfully in multiple contexts, both before and after the March 1993 date, the very expanded motifs described in the specification herein have been used in this way. Attached hereto as Exhibit B is a table providing examples of studies which employed the claimed motifs and methods set forth in the specification. The table is generally self-explanatory. All of the peptides in the table have been verified as immunogenic. As can be seen in the table, many researchers utilized these motifs to identify immunogenic epitopes from a wide variety of antigens, including antigens associated with infectious disease and tumors. The studies reported in the attached table demonstrate that researchers could routinely utilize the motifs elucidated in the present application and successfully identify peptides which elicit a HLA-A2.1 restricted CTL response.

16. For example, Wizel, *et al., J. Clin. Invest.* (1998) 102:1062 used the motifs described herein to identify peptides derived from *Trypanosoma cruzi* to obtain five immunogenic peptides bearing this motif. In another example, Ressing, *et al., J. Immunol.* (1995) 154:5934 utilized this motif to identify two immunogenic peptides.

17. Moreover, the fact that the immunogenic peptides are recognized by CTLs from infected patients, immunized individuals, and naturally exposed individuals also strongly suggests that antigen processing and other factors are not major obstacles to the immunogenicity.

18. In summary, the work discussed above shows that both HLA binding assays and immunogenicity assays were well known and routine in March 1993, and that motif analysis considerably reduces the number of assays needed to identify peptides having the desired HLA binding activity. In addition, the immunogenicity of peptides with the expanded motif described in the specification has been verified.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Executed at San Diego, California, on Nov 15th, 2001.

Alessandro Sette

CURRICULUM VITAE

Name:	Alessandro Sette
Place and date of birth:	Rome, Italy; August 11, 1960
Nationality:	Italian
Visa status:	Permanent Resident Alien
Social Security #:	524-47-5104

Address:	Epimmune Inc. 5820 Nancy Ridge Drive San Diego, CA 92121	Studio Legale Sette 9 Via Puccini Rome, 00198, Italy
Phone:	Work: (858) 860-2500 x2516 Fax: (858) 860-2600 Home: (858) 454-5638	ufficio: (06) 8417230 Fax: (06) 8845935

Education:

1974 - 1979	Humanistic studies at Liceo Classico "T. Tasso" in Rome. Final grade: 60/60.
1979 - 1983	Enrolled in the Department of Biological Sciences of the University of Rome. Average grade: 29.5/30.
February 1984	FEBS Winter School in "Biochemistry of Aging" in Maria Alm (Austria).
March 1984	Advanced course on "Combinatorial Logic and Computer Programming" in the Department of Mathematical Sciences at the University of Rome.
July 1984	Graduated in Biological Sciences (maximum cum laude) with an experimental thesis, realized under the supervision of Prof. G. Doria, on "Age-related changes in radiosensitivity of the immune system."
September 1984	FEBS-NATO-EMBO Summer School on "Genome Organization and Function" in Spetsai (Greece).
February 1992	Liquid Chromatography Course (Beckman), Tucson, Arizona.
June 1992	Tandem Mass Spectrometry Course given by D. Hunt, University of Virginia, Charlottesville, Virginia.
July 1994	Graduated from 6-month intensive program on Leadership and Management (LAMP) at the University of California San Diego (UCSD)
Spring 2001	Courses on Bioinformatics and Biological Databases at the San Diego Supercomputer Center (UCSD)

Working Experience:

Laboratory of Pathology, C.R.E. Casaccia, Rome.

Predoctoral Fellow (Supervisor, Gino Doria), 1983 - 1984.

Postdoctoral Fellow (Supervisor, Luciano Adorini), 1984 - 1985.

National Jewish Center for Immunology and Respiratory Medicine, Denver, Colorado.

Postdoctoral Fellow (Supervisor, Howard Grey), 1986 - 1988.

Laboratory of Pathology of E.N.E.A., Casaccia, Rome.

Biotechnology Consultant in Computer Science, 1986 - 1988.

Exhibit A

Research Institute of Scripps Clinic and Research Foundation, La Jolla, California.

Adjunct Member, Department of Immunology, 1988 -

Cytel Corporation, San Diego, California.

Staff Scientist, 1988 - 1989.

Senior Staff Scientist, 1989 - 1990.

Project Leader of the Autoimmunity Program. This joint program in collaboration with Sandoz Ltd., 1989 - 1992.

Supervisor of Cytel MHC binding assays laboratory, 1989 - 1997.

Associate Director of Immunochemistry, 1990 - 1993.

Member of the Project Team, "Effect of Glycosylation on Peptides' Immunogenicity", 1990 - 1991.

Project Leader of the Food Allergy Program, 1990 - 1991.

Member of the Management Committee, 1992 - 1993.

Director of Immunochemistry, 1993 - 1994.

Project Leader of the Human Papillomavirus Project, 1993 - 1994.

Director of Immunology, 1994 - 1997.

Project Leader of the Fungal Disease Program, in collaboration with Takara Shuzo Co. Ltd., Japan, 1994 - 1997

Member of the Management Committee, 1995 - 1997.

Project Leader of the Technology Development Project, 1995 - 1997.

Epimmune Inc., San Diego, California.

Vice President, Chief Scientific Officer, 1997 -

Issued U.S. Patents and Inventions:

- Method for Identifying Useful Polypeptide Vaccines. U. S. Patent No. 5,200,320, issued April 6, 1993.
- Induction of Anti-Tumor Cytotoxic T Lymphocytes in Humans Using Synthetic Peptide Epitopes. U.S. Patent No. 5,662,907, issued September 2, 1997.
- Immunosuppressant Peptides. U. S. Patent No. 5,679,640, issued October 21, 1997.
- Alteration of Immune Response Using PAN DR-Binding Peptides. U.S. Patent No. 5,736,142, issued April 7, 1998.
- DNA Encoding Mage-1 C Terminal Cytotoxic T Lymphocyte Immunogenic Peptides. U.S. Patent No. 5,750,395, issued May 12, 1998.
- Methods for making HLA Binding Peptides and Their Uses. U.S. Patent No. 6,037,135, issued March 14, 2000.
- Oncogene Fusion Protein Peptide Vaccines. U.S. Patent No. 6,156,316, issued December 5, 2000.

Editorial Responsibilities:

Ad Hoc reviewer for Nature, Science, Cell, Immunity, Journal of Experimental Medicine, Proceedings of the National Academy of Sciences, Cancer Research, Journal of Clinical Investigation , Journal of Immunological Methods, International Immunology, Autoimmunity, , Immunology Today, Biochimica and Biophysica Acta, J.of Virol, and Hepatology.

1992 - 1998	Associate Editor, The Journal of Immunology
1993 -	Peer Review Consultant, National Institutes of Health and National Cancer Institute.
1994 - 1997	Member, Arthritis Foundation Study Section, Cellular Immunology

1996	Ad Hoc Consultant for National Science Foundation, European Science Institute, Instituto Superiore di Sanita', Wellcome Trust, ITN and other funding agencies
1998 - 1999	Member, HIV Vaccines Study Session, National Institutes of Health
1998 - 1999	Editorial Board Member: Human Immunology, Current Pharmaceutical Biotechnology; Current Drugs, Tissue Antigens.

Memberships and Society Affiliations:

Gruppo di Cooperazione in Immunologia, Societa' Italiana di Biometria, Societa' Italiana di Biochimica, American Association of Immunologists, American Association of Microbiologists, American Society for Microbiology, American Chemical Society, The Protein Society, N. Y. Academy of Science, and American Association for Cancer Research

Honors and Awards:

1990	51st Oregon State University Biological Colloquium Award
1994 - 1995	Co-Investigator. Molecular Events in Antigen Recognition, National Institutes of Health grant (H. M. Grey, P.I.).
1994 - 1996	SubProject P.I. Isolation and Characterization of MHC-Bound Self-Peptides in Autoimmune Disease, National Institutes of Health grant (K.S.K. Tung, P.I.).
1994 - 1999	Principal Investigator. A General Strategy for Identification of Broadly Reactive HLA Restricted T Cell Epitopes, NIAID Contract No. NOAI45241.
1995	Member of A. Geluk Ph.D. thesis graduating committee, University of Leiden, The Netherlands.
1995	American Association of Immunologists Investigator Award.
1995 - 1998	Co-Investigator. Development of Peptide-based Immunotherapeutic for AIDS, National Institutes of Health, National Institute of Allergy and Infectious Diseases, SPIRAT Grant. Contract No. U19 AI38584-01/05.
1996 - 1997	Principal Investigator. Vaccine Approaches to Treatment of Hepatitis C Infection, National Institutes of Health, SBIR Grant (Phase I). Contract No. 1R 43 AI38620-01
1996 - 1997	Co-Investigator. Peptide Based Vaccine for Primate Model of AIDS, National Institutes of Health, National Institute of Allergy and Infectious Diseases, SIV Grant (Phase I). Contract No. 1R 43 AI38081-01.
1997 - 1998	Co-Investigator. Processing & Presentation or Lipopeptides and Minigenes, National Institutes of Health, National Institute of Allergy and Infectious Diseases, HIV Grant. Contract No. 1 R21 AI42699-01.
1997 - 1999	Principal Investigator. A Peptide Vaccine for Breast Cancer Prevention, University of California, Breast Cancer Research Program. Contract No. 1RB-0302.
1998 - 1999	Co-Investigator. Peptide Based Vaccine for Primate Model of AIDS, National Institutes of Health, National Institute of Allergy and Infectious Diseases, SIV Grant (Phase II). Contract No. 2R 44 AI38081-02.
1998 -	Member of the Kriegler Lecture and Award Selection Committee
1998 - 2000	Principal Investigator. Vaccine Approaches to Treatment of Hepatitis C Infection, National Institutes of Health, SBIR Grant (Phase II). Contract No. 2R 44 AI38620-03.
1999 - 2004	Principal Investigator. Application of Data on HLA and CD1 to the Improvement of Vaccines, National Institutes of Health, Contract No. N01-AI-95362.
2000 – 2005	Co-Investigator. MHC-Bound, SIV-Derived CTL and Epitopes. National Institutes of Health. Grant # R24 RR 15371.

2000-2004	Co-Investigator. Epitope-Based DNA Vaccines for AIDS Therapy. National Institutes of Health. Grant # PO1-AI-48238 (IPCP).
2001	American Liver Foundation Award for Biotechnology Companies
2002	ISI highly cited investigator (top 200 in the Immunology category over the 1981-2000 period, with over 11,000 Citation Index citations.

PUBLICATIONS

Papers in Scientific Journals:

1. Colizzi, V., Palmieri, G., Sette, A., Appella, E., Doria, G., and Adorini, L. Synthetic peptides in the analysis of the induction and regulation of delayed-type hyper-sensitivity to lysozyme. *Folia Biol.* (Praha) 31:396-401, 1985.
2. Adorini, L., Palmieri, G., Sette, A., Appella, E., and Doria, G. Expression of T-cell receptor by a mouse monoclonal antigen-specific suppressor T-cell line. *Curr. Top. Microbiol. Immunol.* 126:53-61, 1986.
3. Sette, A., Adorini, L., Marubini, E., and Doria, G. A microcomputer program for probit analysis of interleukin-2 (IL-2) titration data. *J Immunol Methods* Feb.; 86(2):265-277, 1986
4. Sette, A., Colizzi, V., Appella, E., Doria, G., and Adorini, L. Analysis of lysozyme-specific immune responses by synthetic peptides. I. Characterization of antibody and T cell-mediated responses to the N-terminal peptide of hen egg-white lysozyme. *Eur J Immunol* 16:1-6, 1986.
5. Sette, A., Doria, G., and Adorini, L. A microcomputer program for hydrophilicity and amphipathicity analysis of protein antigens. *Mol. Immunol.* 23:807-810, 1986.
6. Buus, S., Sette, A., Colon, S. M., Jenis, D. M., and Grey, H. M. Isolation and characterization of antigen-Ia complexes involved in T cell recognition. *Cell* 47:1071-77, 1986.
7. Guillet, J.-G., Lai, M.-Z., Briner, T. J., Buus, S., Sette, A., Grey, H. M., Smith, J. A., and Gefter, M. L. Immunological self, nonself discrimination. *Science* 235:865-870, 1987.
8. Buus, S., Sette, A., Colon, S. M., Miles, C., and Grey, H. M. The relation between major histocompatibility complex (MHC) restriction and the capacity of Ia to bind immunogenic peptides. *Science* 235:1353-58, 1987.
9. Sette, A., Buus, S., Colon, S., Smith, J. A., Miles, C., and Grey, H. M. Structural characteristics of an antigen required for its interaction with Ia and recognition by T cells. *Nature* 328:395-9, 1987.
10. Sette, A., Buus, S., Colon, S., Miles, C., and Grey, H. M. I-A^d-binding peptides derived from unrelated protein antigens share a common structural motif. *J Immunol* 141:45-48, 1988.
11. Adorini, L., Sette, A., Buus, S., Grey, H. M., Darsley, M., Lehmann, P. V., Doria, G., Nagy, Z. A., and Appella, E. Interaction of an immunodominant epitope with Ia molecules in T-cell activation. *Proc Natl Acad Sci* USA 85:5181-85, 1988.
12. Sette, A., Adorini, L., Mancini, C., Marubini, E., and Doria, G. Computerized data analysis in cellular immunology. Enhancement and suppression of immune responses. *J Immunol Methods* 112:91-98, 1988.
13. Buus, S., Sette, A., Colon, S. M., and Grey, H. M. Autologous peptides constitutively occupy the antigen binding site on Ia. *Science* 242:1045-47, 1988.
14. Sette, A., Doria, G., and Adorini, L. A basic library of microcomputer programs to obtain immunologically relevant information from protein sequences. *Int J Biomed Comput* 22:165-181, 1988.
15. Sette, A., Buus, S., Colon, S., Miles, C., and Grey, H. M. Structural analysis of peptides capable of binding to more than one Ia antigen. *J Immunol* 142:35-40, 1989.
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17. Schaeffer, E. B., Sette, A., Johnson, D. L., Bekoff, M. C., Smith, J. A., Grey, H. M., and Buus, S. Relative contribution of "determinant selection" and "holes in the T-cell repertoire" to T-cell responses. *Proc Natl Acad Sci* USA, 86:4649-53, 1989.

18. Sette, A., Adorini, L., Colon, S. M., Buus, S., and Grey, H. M. Capacity of intact proteins to bind to MHC class II molecules. *J Immunol* 143:1265-67, 1989.

19. Sette, A., Lamont, A., Buus, S., Colon, S. M., Miles, C., and Grey, H. M. Effect of conformational propensity of peptide antigens in their interaction with MHC class II molecules. Failure to document the importance of regular secondary structures. *J Immunol* 143:1268-73, 1989.

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